KnightStar® 330 User's Manual

Bi-Level® Ventilator

Part No. Y-500009-00
Rev. J
June 2006

KnightStar® 330 **User's Manual**

Bi-Level® Ventilator

This space for Home Care
Provider's Business Card

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Introduction

The Puritan Bennett *KnightStar*® *330* Bi-Level® Ventilator assists patients who are being treated for respiratory insufficiency or Obstructive Sleep Apnea (OSA) in the home, hospital, or institutional setting. It is also used to treat respiratory failure in the hospital setting.

The *KnightStar 330* is designed to prevent the upper airway from being obstructed by delivering air pressure through an interface (mask or nasal pillows) using one of three different modes; Inspiratory/Expiratory Positive Airway Pressure (I/E PAP), Assist Control (A/C), or Continuous Positive Airway Pressure (CPAP).

I/E PAP mode allows you to breathe at separate inspiratory and expiratory pressure levels, while CPAP mode provides a single, continuous breathing pressure. These pressure levels are set by your clinician so that they provide enough pressure to keep the airway open while maintaining a comfortable breathing effort while you sleep. A/C mode ventilates patients just as I/E PAP mode with the additional features of a settable backup ventilation respiratory rate and I:E ratio.

Patients using the *KnightStar 330* should weigh at least 30 kg (66 lbs) and be able to breathe on their own.

Read this entire booklet before using the *KnightStar 330*. It will help you use the device safely and effectively. If you have any questions about the device or its use, contact your physician or home care provider.

1.1   Warnings, Cautions, and Notes

The following words and symbols found in this manual have special significance:

Warnings alert the user to potential serious outcomes (death, injury, or adverse events) to the patient or user.

Cautions alert the user to exercise care necessary for the safe and effective use of the *KnightStar 330*.

Notes indicate information of particular interest for more efficient and convenient operation.

Review the following messages prior to using the *KnightStar 330*:

When using this equipment, it is important that you read, understand, and follow the instructions and warnings in this user's manual.

There is no *audible* alarm built into the *KnightStar 330* to indicate that the patient has stopped breathing.

Under certain conditions, some alarms may not occur. For example: (1) the leak alarm may not occur if patient breath efforts are not detected, as in the case of excessively large leaks; and (2) the low pressure alarm may not occur under conditions such as an incorrect alarm threshold setting or air pathway resistance.

This product is intended for use only as prescribed by a physician.

The *KnightStar 330* and all other bi-level pressure devices should only be used with interfaces and breathing circuits recommended by the device's manufacturer or by your physician.

An interface should not be used unless the device is turned on and operating properly. When the device is turned on and functioning properly, fresh air from the device flushes the exhaled air out through the interface vent hole(s). However, when the device is not operating, a substantial proportion of exhaled air, including carbon dioxide (CO_2) may be rebreathed. Prolonged rebreathing of carbon dioxide can increase CO_2 levels and, in some circumstances, may even result in death. **DO NOT BLOCK THE INTERFACE VENT HOLE(S).**

At low pressure settings, the flow through the vent hole may be inadequate to clear all exhaled air from the tubing. Some rebreathing may occur.

For your health and comfort, clean the *KnightStar 330*, interface, and breathing circuit regularly before use. Refer to Section 3.5, on page 3-11, or follow the cleaning instructions that came with your interface and breathing circuit.

Set up the *KnightStar 330* system as shown in this manual for safe and effective operation.

To reduce the risk of strangulation, be sure to route the tubing away from the head.

Keep the breathing circuit and power cord away from heated surfaces.

Patients who receive supplemental oxygen should be aware that hazards exist with combustible materials and flames or sparks in the presence of oxygen. Do not smoke in the presence of oxygen.

At a fixed flow rate of supplemental oxygen, the inhaled oxygen concentration will vary depending upon pressure settings, patient breathing patterns, mask or nasal interface selection, and leak rate.

Explosion Hazard - This equipment is not suitable for use in the presence of a flammable anaesthetic mixture with air, or with oxygen or nitrous oxide.

The *KnightStar 330* should never be operated where gases from external sources, gas stoves, engine exhaust, or anesthesia machines could be combined with air at the inlet. Placing the unit in such an area may result in asphyxiation.

To avoid electrical shock:

- **Do not use if power cord or plug is damaged**
- **Unplug all power cords before cleaning**
- **Do not use near water such as sinks, showers or bathtubs, where water could spill onto the device**
- **If you suspect that water has entered the *KnightStar 330*, unplug the power cord and let device dry before using**

Never drop or insert any object into the air outlet or any other opening on the unit or breathing circuit.

Should you experience nasal or airway dryness, skin sensitivity, runny nose, ear pain, sinus discomfort, daytime sleepiness, mood change, disorientation, or memory lapse when using this device, discontinue use and call your physician.

Contact your home care company if the equipment malfunctions in any way. Do not attempt to open the device case. Only qualified personnel may service this equipment.

If the display indicators on the unit are inoperative, the unit must be checked by the proper personnel.

Always place the *KnightStar 330* upright on a firm, flat surface, and use only approved accessories. Placing the device on uneven surfaces, using it in an improper orientation, or using unapproved accessories could result in the device tipping over, causing damage or possible patient injury.

The *KnightStar 330* should be used with care to avoid overheating the patient when the room temperature exceeds 90°F (32.2^{o}C), since under certain conditions the patient outlet gas flow can be as much as 6.7^{o}F (3.7^{o}C) degrees warmer than room temperature.

The *KnightStar 330* equipment has been tested and found to comply with the limits for medical devices to IEC 601-1-2:2001 (or EN 60601-1-2:2001 or Medical Device Directive 93/42/EEC). This testing shows the device provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation, for example, in the presence of portable and mobile RF communication devices. If this equipment does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- **Reorient or relocate the devices**
- **Increase the separation between the devices**
- **Connect the equipment to an outlet on a different circuit**
- **Consult the manufacturer or field service technician for help**

Do not set the *KnightStar 330* on or within 3 feet (1 m) of electric or electronic appliances, such as space heaters, electric blankets, or televisions. Do not operate cordless phones near the device. Doing so may result in device malfunction.

Be careful when handling the *KnightStar 330* during or immediately after use. Under specified operating conditions, some surfaces of the unit may become hot to the touch. This is a normal occurrence and is typical of this type of device.

Always operate the *KnightStar 330* with the outlet filter in place. Failure to do so could increase your risk of infection or contaminant inhalation.

Inspect the inlet air filter often. Remove the foam filter from the rear panel and clean it at least once per week, or more often in dusty environments. Let the filter air dry completely before reinstallation.

See Section 3.5.3 on page 3-12 for information on cleaning the inlet air filter.

Start the *KnightStar 330* system before putting on the interface.

Federal (USA) law restricts this device to sale by or on the order of a physician.

At the end of the *KnightStar 330's* useful life, return the device to the manufacturer for proper disposal.

1.2 System controls and indicators

The following sections help you to become familiar with the *KnightStar 330* control panel and indicators, and describe the various symbols displayed on the device's labels and LCD screen.

The *KnightStar 330* control panel keys and indicators are shown in Figure 1-1 and described in Table 1-1.
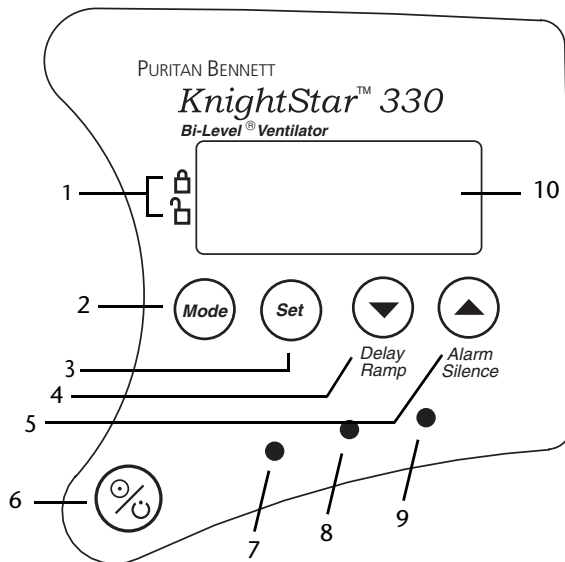

Figure 1-1. *KnightStar 330* **control panel**

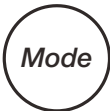## Table 1-1: *KnightStar 330* control panel keys and indicators
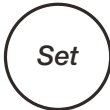
Key or indicator (Figure 1-1)	Labeling	Function
1	🔒🔓	Access mode indicator 🔒 ← Indicates the *KnightStar 330* is in Patient access mode. 🔓 ← Indicates the *KnightStar 330* is in Clinician access mode. Patient access mode prevents accidental changes to the settings prescribed by your physician, and allows you to change the delay time, ramp duration, and ramp start pressure. Clinician access mode allows your physician to program the prescribed breathing mode, pressure(s), and other settings into the device.
2	*Mode*	Mode key Press the Mode key to leave the Settings mode after changing the delay time, ramp duration, or ramp start pressure settings. Pressing this key also turns on the LCD panel backlight. In Clinician access mode, the Mode key is used to set the breathing mode to A/C, CPAP, or I/E PAP.
3	*Set*	Settings key Press the Settings key repeatedly to enter the Settings mode and scroll through the delay time, ramp duration, and ramp start pressure options (shown on the LCD panel as → DELAY, → RAMP, and → STRT P). Pressing this key also turns on the LCD panel backlight.

### Table 1-1: *KnightStar 330* control panel keys and indicators (continued)

Key or indicator (Figure 1-1)	Labeling	Function
4	▼ *Delay Ramp*	Down Arrow & Delay/Ramp key Use the Down Arrow key to decrease a selected setting value when setting the delay time, ramp duration, or start pressure. If not in Settings mode, use this key to start or stop the Delay/Ramp function. The _◢ symbol appears in the lower left corner of the LCD panel when the delay/ramp function is active.
5	▲ *Alarm Silence*	Up Arrow & Alarm Silence key Use the Up Arrow key to increase a selected setting value in Settings mode. If not in Settings mode, use this key to mute an active alarm for one minute. In I/E mode, when the main display screen is shown, pressing this key displays V̇ (peak inhalation flow) and I:E ratio (ratio of inhalation time to exhalation time) if there are no active alarms.
6		On/Off key Turn the *KnightStar 330* system on with a quick press and release action. To turn the device off, **press and hold** the On/Off key for 3 seconds. The *KnightStar 330* retains in memory the settings last entered.
7	Green LED	When lit, indicates the presence of power, whether from Mains/AC or external battery (Stand-by mode).

Table 1-1: *KnightStar 330* control panel keys and indicators (continued)

Key or indicator (Figure 1-1)	Labeling	Function
8	Yellow LED	When steadily lit and accompanied by the ƒ↓ symbol displayed in the lower left corner of the LCD panel, indicates a LOW PRIORITY alarm condition.
		When flashing, indicates a MEDIUM PRIORITY alarm condition accompanied by an audible alarm signal (3 beeps at intervals of approximately 25 seconds).
		Refer to Chapter 4 How to solve device problems for causes and corrections for alarm conditions.
9	Red LED	When flashing, indicates a HIGH PRIORITY alarm condition accompanied by an audible alarm signal (a series of 3 beeps, then 5 beeps, then 2 beeps at intervals of approximately 6 seconds). Refer to Chapter 4 How to solve device problems for causes and corrections for alarm conditions.
10	Liquid Crystal Display (LCD)	The LCD provides an easy-to-read format for mode, settings, and patient data. A backlight illuminates the display when the Mode, Settings, or Up arrow key is pressed. The display will remain lit for approximately 60 seconds after the last key is pressed.

1.3   *KnightStar 330* **connectors**

Figures 1-2 and 1-3 and Tables 1-2 and 1-3 identify and describe the connectors and their identifying symbols found on the *KnightStar 330*.
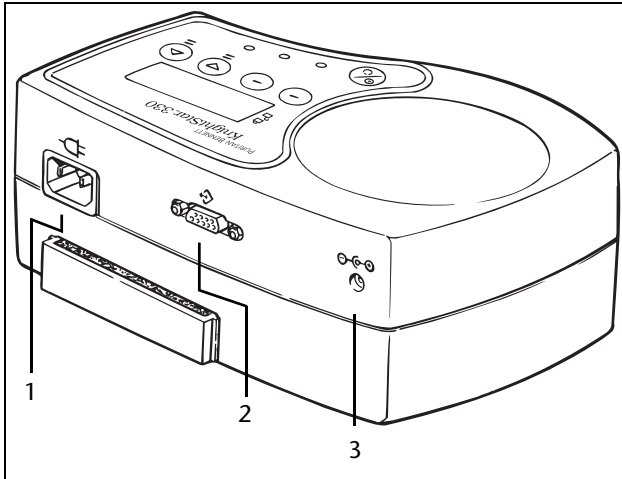
Figure 1-2. *KnightStar 330* rear view

Table 1-2: *KnightStar 330* rear panel connectors
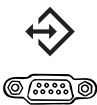
Index (Figure 1-2)	Symbol	Description
1		Mains/AC power receptacle The *KnightStar 330* operates on 100V to 240 V AC at 50 or 60 Hz.

Table 1-2: *KnightStar 330* **rear panel connectors (continued)**

Index (Figure 1-2)	Symbol	Description
2		RS-232 (serial) port This connector is used for communications with other devices such as a personal computer (PC).
3		External battery connector Used to connect an optional external 12 V DC battery, or for use with a 12 V automobile cigarette lighter adapter when Mains/AC power is not available.
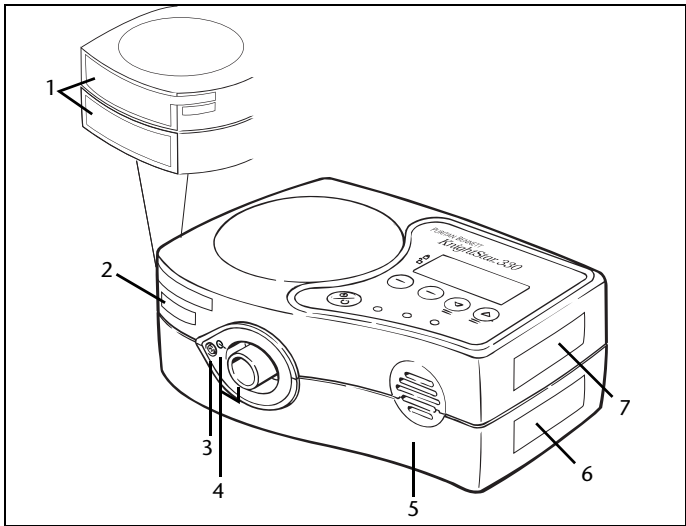
Figure 1-3. *KnightStar 330* front and side view

Table 1-3: *KnightStar 330* front panel connectors and labeling

Index (Figure 1-3)	Labeling	Description
1	Troubleshooting label	Contains information on how to respond to some alarms.
2	O₂ ⚠ See Operator's Manual for use with oxygen	Refer to manual for information on using the ventilator with oxygen.
3	N/A	Patient pressure tube connector
4	⊙→	Air outlet connector (22 mm conical fitting)
5	N/A	Alarm speaker

Table 1-3: *KnightStar 330* **front panel connectors and labeling (continued)**

Index (Figure 1-3)	Labeling	Description
6	Note The patient outlet gas flow can be as much as 7° F (4°C) degrees warmer than room temperature.	Notifies user to refer to the manual (page 1-6) regarding increased outlet gas flow temperature.
7	Warning label	Warns user that the ventilator can become hot to the touch.

1.4 *KnightStar 330* symbols

1.4.1 Bottom panel label symbols

Figure 1-4 and Table 1-4 describe the symbols found on the *KnightStar 330*'s bottom panel label.
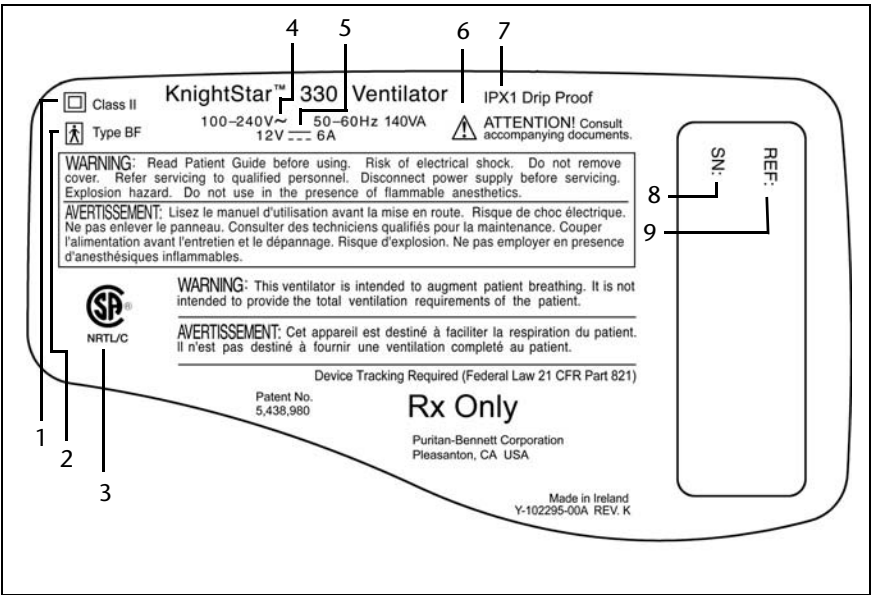
Figure 1-4. *KnightStar 330* **bottom panel label**

Table 1-4: *KnightStar 330* bottom panel label symbols

Index (Figure 1-4)	Labeling	Description
1		Class II equipment A regulatory standard classification for protection against electric shock. Class II equipment relies on DOUBLE INSULATION rather than protective earthing.
2		Type BF equipment A regulatory standard classification for protection against electrical shock for the part of the device that contacts the patient.
3	NRTL /C	Authorized to bear the CSA certification mark, signifying the product has been evaluated to the applicable CSA standards for use in the US and Canada. UL2601-1 CAN/CSA C22.2 No. 601.1- M90
4		Alternating current (Mains/AC power from wall outlet)
5		Direct current (battery power)
6		Attention! Consult accompanying documents.
7	IPX1	Drip proof A regulatory standard classification for protection against dripping water.
8	SN	Serial number
9	REF	Model number

1.4.2   Onscreen symbols

Table 1-5 describes the symbols that appear on the LCD panel during device set-up and when the *KnightStar 330* is operating.

Table 1-5: *KnightStar 330* **LCD panel symbols**

Symbol or abbreviation	Definition
START-UP DISPLAY SYMBOLS	
ON TIME	Total hours of operation
USAGE	Total compliance time (usage in hours)
SN	Serial number
ID	Patient identification number (12 digits)
MODES	
A/C	Assist Control mode
I/E	Inspiratory/Expiratory Positive Airway Pressure mode
CPAP	Continuous Positive Airway Pressure mode and pressure setting
MEASURED VALUES	
f	Respiratory rate
P	Current pressure
Vt	Tidal Volume
L	Leak rate

Table 1-5: *KnightStar 330* **LCD panel symbols (continued)**

Symbol or abbreviation	Definition
V̇	Peak inhalation flow
I:E	Ratio of inspiration time to expiration time
SETTINGS	
IPAP	Inspiratory pressure
EPAP	Expiratory pressure
BACKUP f	Backup respiration rate (in A/C mode)
I:E	I:E ratio
ISENS	Inspiratory sensitivity
ESENS	Expiratory sensitivity
RISE	Rise time setting
◁⟩VOL	Alarm volume level
LEAK◁⟩	Leak alarm setting
LO P◁⟩	Low pressure alarm setting
HI P◁⟩	High pressure alarm setting
DELAY	Delay time
RAMP	Ramp duration
STRT P	Ramp start pressure
MASK L	Interface (mask) leak/type (1-6)

Table 1-5: *KnightStar 330* **LCD panel symbols (continued)**

Symbol or abbreviation	Definition
ALARMS	
◁〉P↑	High pressure alarm condition
◁〉P↓	Low pressure alarm condition
◁〉L↑	Leak alarm condition
f↓	Backup respiratory rate active (apnea)
◁〉# #	Malfunction (one or two digit error code, ##, denotes error type)
STATUS	
▬◢	Ramp delay active
🔒←	Patient access mode
🔓←	Clinician access mode
◁⟩	Alarm is silenced

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Getting started

The *KnightStar 330* has been prescribed to assist your breathing by supplying air through a flexible tube (called a breathing circuit) connected to a mask or nasal interface.

The regimen for the treatment of your disease is prescribed by your physician. Your physician has prescribed various settings that are preset into the product. Unless otherwise directed by your physician, you will not need to make any adjustments.

To begin using the *KnightStar 330*, you will need:

•   an interface (either nasal pillows or a mask)

•   a breathing circuit to deliver air flow to your nose

The *KnightStar 330* is designed to be used with standard 6-ft (1.8 m), or optional 8-ft (2.4 m) breathing circuits and Puritan Bennett non-invasive interfaces. Breathing circuits, nasal pillows, and masks are available from your home care provider.

Never block the vent hole(s) in the interface.

With your physician or caregiver, review the special information contained in Table 5-1, "Patient and caregiver checklist," on page 5-1 before using the *KnightStar 330.*

2.1 *KnightStar 330* system and components

Figure 2-1 shows the *KnightStar 330* system and its included accessories. The interface (mask or nasal pillows) is supplied separately.

KnightStar 330 Bi-Level Ventilator
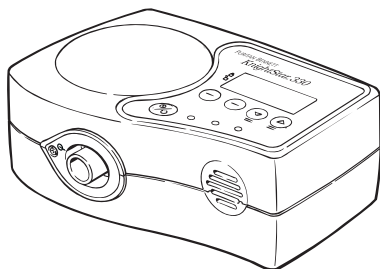
Power cord
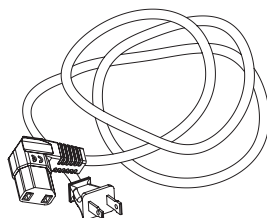
Breathing circuit and patient pressure line
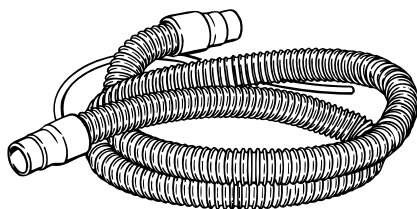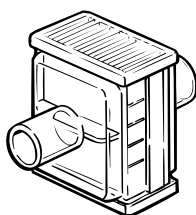
Outlet filter
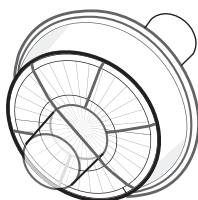
Spare inlet air filter

or

Figure 2-1. *KnightStar 330* components

Make sure that you have all of the components shown in the figure. If anything is missing, contact your homecare provider.

- *KnightStar 330* **Bi-Level Ventilator** — Provides continuous air flow during sleep at pressures prescribed by your clinician. Monitors breathing parameters such as respiratory rate, pressure, tidal volume, peak inhalation flow, leak rate, and I:E ratio.

- **Power cord** — Connects the *KnightStar 330* to AC power only. To connect the *KnightStar 330* to DC (battery) power, special cables are required (see Section 3.4 on page 3-10 for information on using the *KnightStar 330* with an external battery).

- **Breathing circuit and patient pressure line** — The breathing circuit directs air from the *KnightStar 330* to the interface worn by the patient. The patient pressure line is the small tube that runs along the inside of the breathing circuit. This tube is part of the pressure measurement system that controls the output pressure of the *KnightStar 330*.

- **Outlet filter** — The outlet filter removes small contaminants and bacteria from the outlet air. This single-patient use filter removes particles and microbes as small as 0.2 microns. This filter is disposable, and should be replaced in accordance with the filter manufacturer's instructions. Be sure to inspect the filter regularly and replace it when noticeably dirty or discolored. Frequency of replacement can vary, depending on usage and environmental conditions (replace more frequently in dusty environments). Contact your home care provider for replacement filters.

- **Spare inlet air filter** — The inlet air filter is pre-installed in the *KnightStar 330* and screens out particles from the incoming air. A spare inlet air filter is provided for use when the original filter needs to be cleaned or replaced. (See Section 3.5.3 on page 3-12 for information on cleaning the inlet air filter.)

2.2   System setup

The *KnightStar 330* requires minimal effort to set up and use. Set-up consists of:

- Cleaning the device and breathing circuit prior to first use
- Connecting the device to AC power
- Connecting the breathing circuit, outlet filter, and mask or nasal interface

2.2.1   Before first use

Before using the *KnightStar 330* for the first time, clean the breathing circuit and the outer surfaces of the device according to the instructions in Section 3.5 on page 3-11.

> **Always unplug the *KnightStar 330* from all electrical power sources before cleaning. Do not let water drip into any opening on the unit.**

2.2.2   How to connect to AC power

To connect to AC power:

1. Place the *KnightStar 330* on a stable, flat surface near the bedside with at least 1 in. (2.5 cm) of clearance at the back of the device to allow proper air flow into the air inlet.

2. Attach one end of the power cord to the AC receptacle at the back of the *KnightStar 330* and the other end of the cord to an electrical outlet. The green LED should appear, letting you know that the device is now in Stand-by mode.

To use the *KnightStar 330* with an external battery, see Section 3.4 on page 3-10.

2.2.3   How to connect the breathing circuit, outlet filter, and mask

To connect the breathing circuit, outlet filter, and mask or nasal interface to the *KnightStar 330* (refer to Figure 2-2):

① Attach patient pressure tube to pressure connector

② Attach filter to air outlet connector

③ Attach breathing circuit to filter
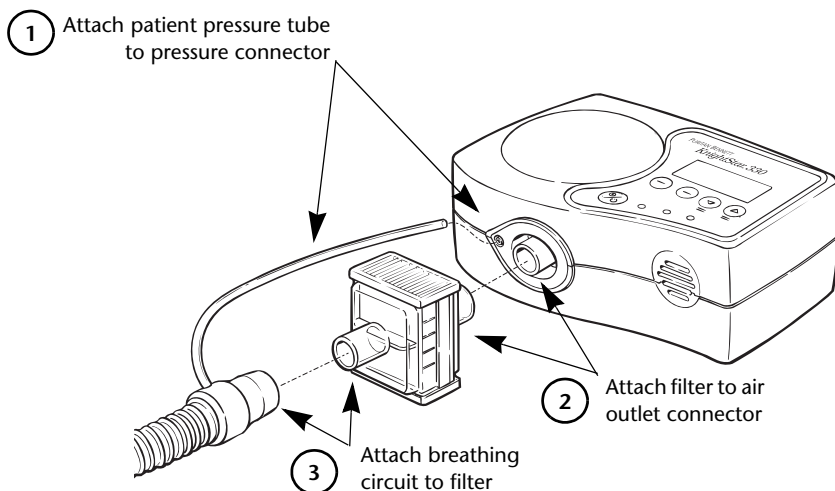
Figure 2-2. How to connect the breathing circuit and filter

1. Attach the breathing circuit patient pressure tube to the corresponding connector on the front of the device.

2. Push the larger end of the outlet filter onto the *KnightStar 330*'s air outlet connector.

> ⚠ **Always operate the *KnightStar 330* with the outlet filter in place. Failure to do so could increase your risk of infection or contaminant inhalation.**

3. Push the end of the breathing circuit over the outlet filter's connector.

4. Attach the other end of the breathing circuit to the connector on the mask or nasal interface.

The system is now ready to operate.

How to operate the *KnightStar 330*

This section tells you how to operate the *KnightStar 330*. It includes:

- How to operate the ventilator
- How to use supplemental oxygen
- How to use the optional humidifier
- How to run on external battery
- How to clean the device

3.1 Basic operation

To ensure proper operation each time the device is turned on, the Power On Self-Test (POST) automatically runs. During this approximately 9-second period before normal operation begins, the screen illuminates and displays the copyright notice, manufacturer's name, firmware version, total hours of operation, total patient usage hours, device serial number, and patient ID. This is a signal to you that the *KnightStar 330* is operating correctly. If this sequence does not run properly, call your homecare provider for service. When POST has completed, the main screen appears and displays the breathing mode, breath rate (f) in breaths per minute (BPM), pressure (P) in cmH$_2$O, tidal volume (Vt) in mL and leak (L) in liters per minute (LPM).

Follow these instructions for using your *KnightStar 330* system at home:

1. With the *KnightStar 330* set up near the bedside, and the components assembled as described in Section 2.2.3 on page 2-5, press and release the On/Off key to start the *KnightStar 330*.

> • Always start the *KnightStar 330* system before putting the interface on.
>
> • Notice if the symbol ◢ appears in the lower left corner of the LCD panel after you turn the device on. If the symbol appears, a delay has been set and is active. If the symbol is not present, the ventilator supplies the prescribed pressures immediately.

2. Put on your mask or nasal interface, making sure it is securely connected to the breathing circuit.

3. Adjust the breathing circuit so that it will not pull on the interface when you lie down. Adjust the headgear and interface until you are comfortable.

4. Relax and take slow deep breaths through your nose. The *KnightStar 330* will provide ventilatory support continuously until you turn it off.

To turn the *KnightStar 330* off, ***press and hold*** the On/Off key for three seconds.

3.1.1 How to set the Delay/Ramp

The Delay/Ramp feature enables you to delay the start of ventilation and reduce the start pressure at the beginning of the night to make it more comfortable for you to fall asleep. You can also use the delay if you have to get up at night and have trouble going back to sleep.

• **Delay time** — The delay time gives you time to fall asleep before the *KnightStar 330* automatically starts to increase the delivered air pressure to the pressure prescribed by your physician. The delay time can be set from 0 (off) to 30 minutes in 5-minute increments, and is indicated by the symbol DELAY on the LCD panel.

• **Ramp duration** — When the delay time has elapsed, the *KnightStar 330* automatically starts to increase the

pressure over a period of time until it reaches the prescribed pressure. This period of time is the ramp duration. The ramp duration can be set from 0 (off) to 30 minutes in 5-minute increments and is indicated by the symbol RAMP on the LCD panel.

• **Ramp start pressure** — The ramp start pressure is the pressure at which the *KnightStar 330* delivers air flow during the delay period. It can be set from $3 - 20$ cmH$_2$O, but cannot be set higher than the EPAP (in I/E PAP and A/C modes) or CPAP (in CPAP mode) pressure setting. The ramp start pressure is indicated by the symbol STRT P on the LCD panel.

Your clinician may have already set these options for you, in which case no adjustment is needed. If, however, you want to change the settings to improve your comfort level, follow these steps:

1. Turn the *KnightStar 330* on by pressing and releasing the On/Off key.

2. Enter Settings mode by pressing the Settings key until you see the arrow on the LCD panel point to DELAY.

> You can leave Settings mode at any time by pressing the Mode key, repeatedly pressing the Settings key until the main screen appears, or by not pressing any key for 60 seconds.

3. Press the Up or Down Arrow keys to set the desired delay time.

4. Press the Settings key so that the arrow on the LCD panel points to RAMP.

5. Press the Up or Down Arrow keys to set the desired ramp duration.

Set

6. Press the Settings key so that the arrow points to STRT P on the LCD panel.

▲ ▼

7. Press the Up or Down Arrow keys to set the desired ramp start pressure.

Mode

8. Exit Settings mode. The LCD panel displays this symbol $\llcorner\blacktriangleleft$ in the lower left corner, indicating that the delay is active, and the *KnightStar 330* delivers air flow at the ramp start pressure. When the delay time has elapsed, the *KnightStar 330* gradually increases the pressure over the ramp duration until the prescribed pressure is reached.

3.1.2 How to de-activate and activate the Delay/Ramp feature

The Delay/Ramp feature can be used only if values for the delay time, ramp duration, and ramp start pressure are set. The delay will automatically start when the device is turned on. Follow these steps to de-activate or activate the Delay/ramp sequence:

▼

Delay Ramp

1. If the Delay/Ramp feature is already active, press the down arrow/ramp key. The Delay/Ramp symbol $\llcorner\blacktriangleleft$ in the lower left corner of the LCD panel disappears, indicating that the delay is inactive. When de-activated, the *KnightStar 330* starts delivering the prescribed pressures immediately.

2. Press the down arrow (Delay/Ramp) key again to activate the Delay/Ramp feature and restart the delay time.

> If the delay time has been set to 0 (no delay), the Delay/Ramp feature is inactivated, and pressing the Down Arrow (Delay/Ramp) key has no effect.

3.2 How to use the *KnightStar 330* with supplemental oxygen

If your physician determines that you need supplemental oxygen, an oxygen source may be connected to the mask if it is equipped with an oxygen port, or to the device, using a special oxygen adapter available from your homecare provider.

> **Patients who receive supplemental oxygen should be aware that hazards exist with combustible materials and flames or sparks in the presence of oxygen. Oxygen vigorously accelerates combustion. Do not smoke or have an open flame in the presence of oxygen.**

Perform the following steps if you are using a mask or interface equipped with an oxygen port:

1. Connect the oxygen supply tubing to the oxygen port on the interface.

2. Turn the *KnightStar 330* on **before** turning on the oxygen supply.

3. Turn on the oxygen flow at the desired setting.

4. When turning off the *KnightStar 330*, turn off the oxygen supply **first,** then turn off the *KnightStar 330*.

To use supplemental oxygen with the *KnightStar 330* oxygen adapter:

1. Connect the oxygen adapter to the *KnightStar 330* filter outlet (refer to Figure 3-1).

2. Connect the oxygen supply tubing to the small port on the oxygen adapter, as shown in Figure 3-1.

3. Turn the *KnightStar 330* on **before** turning on the oxygen supply.

4. Turn on the oxygen flow at the desired setting.

> ⚠ **Do not use supplemental oxygen at flows above 15 L/min. Doing so could increase the oxygen concentration inside the device and increase the risk of fire.**

5. When turning off the *KnightStar 330*, turn off the oxygen supply ***first,*** then turn off the *KnightStar 330*.

> ⚠ **To prevent oxygen from accumulating in the device and tubing, turn on the device before turning on the oxygen supply; shut off the oxygen before turning off the device.**

O$_2$ port connection
Connect O$_2$ tubing here

Outlet filter
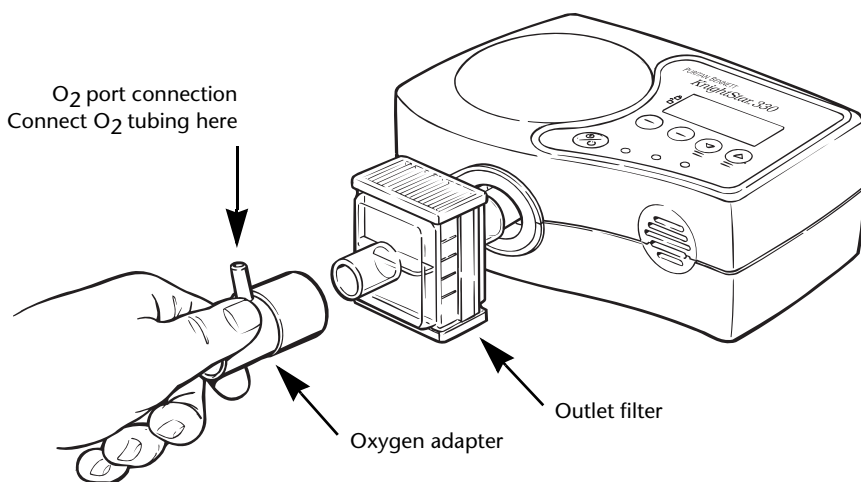
Oxygen adapter

Figure 3-1. How to connect the oxygen adapter to the outlet filter

3.3   How to use the optional humidifier

A humidifier may be used with the *KnightStar 330* if you are experiencing nasal discomfort due to low moisture content in the input air.

Do not allow water to spill onto the *KnightStar 330* or other electrical apparatus. To prevent electrical hazard, remove the source of power if water is suspected of entering the *KnightStar 330*. Do not fill the reservoir when it is in the housing. Use only distilled or sterile water to fill the reservoir.

For information regarding operation, connection, and cleaning, refer to the instructions included with the humidifier.

To use the humidifier, follow these steps:

1. Place the *KnightStar 330* on top of the humidifier housing and its reservoir (Figure 3-2).

Reservoir inlet

Humidifier housing
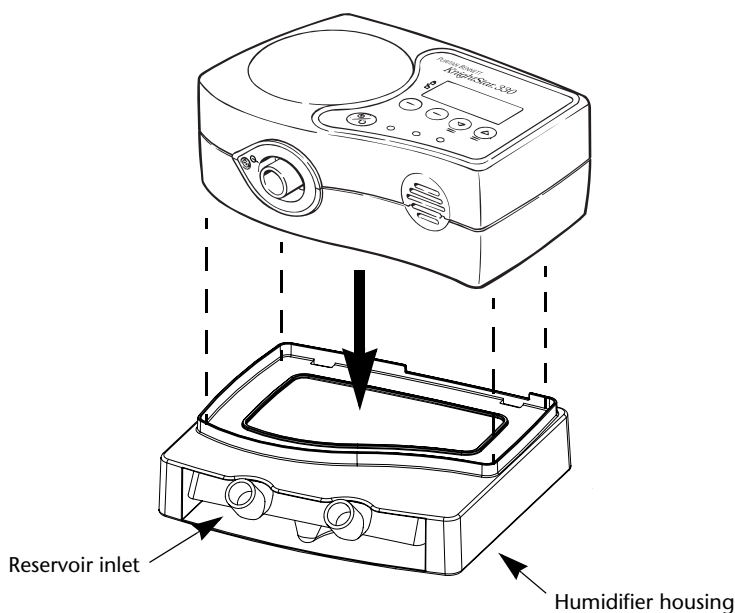
Figure 3-2. How to place the *KnightStar 330* onto the humidifier housing

2. Remove the reservoir from the housing and fill it to the FILL LINE with distilled or sterile water. The reservoir is designed to hold water for only one night's use.

Fill line
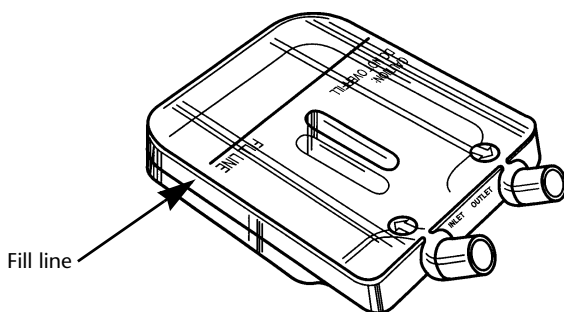
Figure 3-3. Humidifier reservoir

3. Gently slide the reservoir back into the housing.

4. Connect the short humidifier tubing (Figure 3-4) between the *KnightStar 330's* filter outlet and the inlet of the reservoir.

Humidifier tubing connected to reservoir inlet and outlet filter
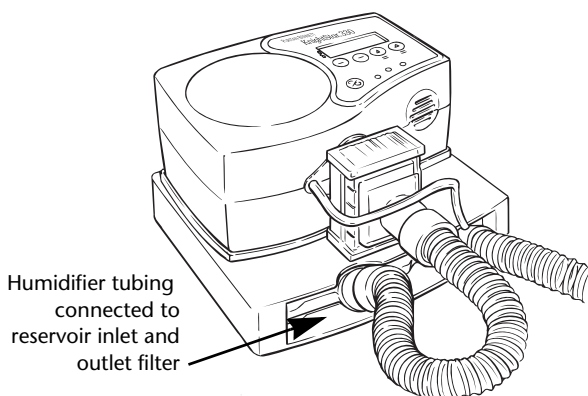
Figure 3-4. How to connect the humidifier tubing

5. Connect the breathing circuit to the humidifier outlet as shown in Figure 3-4. Be sure to connect the patient pressure tube to the connector next to the *KnightStar 330's* air outlet.

> **The *KnightStar 330* should not be used adjacent to or stacked with other equipment, except the humidifier specified in this section. If use adjacent to other equipment is necessary, the *KnightStar 330* should be observed to verify normal operation in the configuration in which it is used.**

3.4 How to use the *KnightStar 330* with an external battery

When power from a wall outlet is unavailable, the *KnightStar 330* can run on DC power from a 12 V external battery, or can be powered using the cigarette lighter/power port in your car or truck.

Puritan Bennett provides two options for external batteries; a 32 ampere-hour battery and a 7 ampere-hour battery. The 32 ampere-hour battery provides up to 8 hours of running time, while the 7 ampere-hour battery provides up to 3 hours of power.

> Actual battery usage times depend upon patient's prescription settings.

Running the *KnightStar 330* on external battery power requires special cables that depend upon whether you are connecting to a Puritan Bennett battery or automobile cigarette lighter/power port. Contact your homecare provider to obtain the correct batteries and cables.

> Use only Puritan Bennett-approved batteries and cables.

To run the *KnightStar 330* using the external battery:

1. Turn the *KnightStar 330* off and disconnect the AC power cord from the back of the device.

2. Connect one end of the appropriate cable to the battery or automobile cigarette lighter/power port and the other end to the external battery connector at the back of the *KnightStar 330* (refer to Figure 1-2 and Table 1-2 on page 1-12).

3. Turn the *KnightStar 330* on.

> Connect the *KnightStar 330* to only one power source at a time; external battery or AC power. Damage to the device can result if connected to both power sources at the same time.

To switch back to AC power:

1. Turn the *KnightStar 330* off and disconnect the battery cable from the back of the device.

2. Connect the AC power cord to the *KnightStar 330* and plug into a wall outlet.

3. Turn the *KnightStar 330* on.

3.5 How to clean the *KnightStar 330*

It is important to clean all of the equipment regularly. Do not use any cleaning method other than described here.

3.5.1 How to clean the breathing circuit

Before you use the breathing circuit for the first time (and at least three times per week thereafter):

1. Plug the ends of the patient pressure line (small tube running along the length of the circuit) with the plugs that came with the circuit.

2. Wash the circuit with warm, soapy, distilled water.

3. Rinse thoroughly with distilled water to remove soap residue.

4. Disinfect according to the instructions for use supplied with your breathing circuit.

5. Allow the breathing circuit to dry. Remove the plugs from the patient pressure line before use.

3.5.2   How to clean the exterior surfaces

Always unplug the *KnightStar 330* from all electrical power sources before cleaning. Do not let water drip into any opening on the unit.

Clean the surfaces of the *KnightStar 330* by wiping with a cloth dampened with warm, soapy water, then wiping dry.

To disinfect the exterior surfaces, you may wipe them with a cloth dampened with:

• Isopropyl alcohol (70% solution), or

• A mixture of 1 part household bleach to 10 parts distilled water (10% solution)

3.5.3   How to clean the inlet air filter

Inspect the inlet filter often by removing the inlet baffle (removable plastic cover on the back of the unit). Clean the filter once a week or more often in dusty environments.

Replace the inlet filter if torn or damaged in any way.

1. Remove the baffle from the back of the unit (Figure 3-5) by pulling outward on the middle of the baffle while pushing one end toward the center.

2. Remove the inlet filter and wash it in warm, soapy, distilled water.

3. Rinse filter well with distilled water to remove all soap.

4. Pat filter dry with a towel.

5. Let the filter dry completely before reinstalling.

6. Reinstall the clean, dry filter or install the spare inlet filter as a replacement.

7. Reattach the inlet baffle by first inserting one end into the housing, then snapping the other end into place.
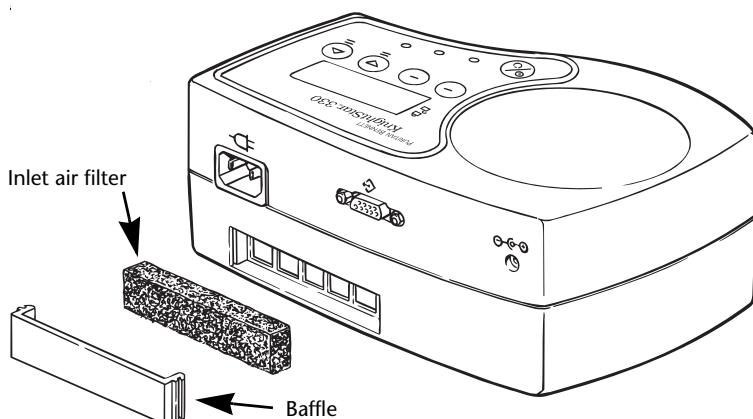

Figure 3-5. Removing the inlet baffle

3.5.4 Outlet filter replacement

The outlet filter is disposable, and should be inspected regularly and replaced when noticeably dirty or discolored, and in accordance with the filter manufacturer's instructions. Frequency of replacement can vary, depending on usage and environmental conditions (replace more frequently in dusty environments). For optimal performance with the *KnightStar 330*, use only Puritan Bennett-approved filters. Contact your home care provider for replacement filters.

3.6   Periodic maintenance

The *KnightStar 330* requires maintenance at regular intervals to ensure that it operates at peak performance. Refer to Table 3-1 for the required maintenance activities and intervals.

Table 3-1: Periodic maintenance schedule

Interval	Item	Maintenance
As needed	Outer surfaces of the *KnightStar 330* ventilator	Clean surfaces with cloth dampened with warm soapy water or disinfectant described in Section 3.5.2. Wipe dry. Do not let liquid drip into any openings in the device.
Weekly	*KnightStar 330* air inlet filter	Inspect filter. Replace if damaged. See Section 3.5.3 for cleaning instructions.
As needed. Frequency of replacement can vary, depending on usage and environmental conditions	Outlet particulate/ bacteria filter	Replace. Contact your homecare provider to order more filters.
Every 24 months	Main blower assembly	Contact your homecare provider.

How to solve device problems

Any unusual system event results in one or all of the following:

- Error code display or alarm symbol
- LED illumination
- Audible alarm

> To mute an alarm for one minute, press the ▲/Alarm Silence key.

Alarms are classified by priority:

- HIGH priority—Indicated by a flashing RED LED accompanied by an audible alarm signal (a series of 3 beeps, then 5 beeps, then 2 beeps at intervals of approximately 6 seconds).
- MEDIUM priority—Indicated by a flashing YELLOW LED accompanied by an audible alarm signal (3 beeps at intervals of approximately 25 seconds).
- LOW priority—Indicated by a steadily lit YELLOW LED on the control panel and no audible alarm.

In many cases, the alarm condition can be remedied by patient or caregiver intervention.

> **There is no *audible* alarm built into the *KnightStar 330* to indicate that the patient has stopped breathing.**

Table 4-1 lists some possible problems and ways to correct them.

Table 4-1: Troubleshooting checklist

Problem	Indicators	Possible Cause	Corrective Action
No airflow out of device	No alarm or displayed symbol.	1. Internal electronic failure. 2. Corrupted prescription settings.	1. Contact your home care provider for repair. 2. Contact your home care provider.
Low airflow out of device	No alarm or displayed symbol.	1. Delay feature activated. 2. Blocked device air inlet. 3. Internal electronic problem.	1. De-activate the delay feature. 2. Move rear of device away from the wall and all objects. 3. Contact your home care provider for repair.
Power loss	Display is blank. Red LED flashes and alarm sounds. No **green** LED.	1. Faulty power cord connection. 2. Wall outlet power failure.	1. Check power cord connections at back of device and wall outlet. 2. Verify AC power is available at wall outlet. If not, connect external battery. Ensure **green** LED on top of device is illuminated.
Overpressure	Alarm and flashing **red** LED. Displayed symbol is 🔊>55.	Internal electronic problem.	Disconnect power for at least 30 seconds; then reconnect to power source. If condition persists, contact your home care provider for repair.

**Table 4-1: Troubleshooting checklist (continued)**

Problem	Indicators	Possible Cause	Corrective Action
High pressure	Alarm and flashing **yellow** LED. Displayed symbol is ⊲>P↑.	Kinked or blocked breathing circuit.	Verify that the breathing circuit has not collapsed, and that there are no sharp bends. Reposition the device, breathing circuit, or accessories, as applicable.
Low pressure	Alarm and flashing **red** LED. Displayed symbol is ⊲>P↓.	1. Breathing circuit leaks or is disconnected. 2. Small patient pressure tube is not connected to port next to device air outlet.	1. Reposition nasal pillows or mask. Check breathing circuit connections at device outlet filter and patient interface. If breathing circuit is punctured or disconnected, replace it or reconnect it, as applicable. 2. Verify proper breathing circuit connection. Disconnect and reconnect, as applicable.
Interface/ mask leak	Alarm and flashing **red** LED. Displayed symbol is ⊲>L↑.	Mask or breathing circuit leaks or is disconnected.	Reposition nasal pillows or mask. Check breathing circuit connections at device outlet filter and patient interface. If breathing circuit is punctured or disconnected, replace it or reconnect it, as applicable.

Table 4-1: Troubleshooting checklist (continued)

Problem	Indicators	Possible Cause	Corrective Action
Low breath rate	No audible alarm. Steady **yellow** LED. Displayed symbol is f↓.	The patient's breath rate is lower than the prescribed setting.	If the patient experiences signs of distress, contact physician.
Internal malfunction	Alarm and flashing **red** LED. Displayed symbol is ⊲⟩# # with ## being a 1- or 2-digit error code.	Internal electronic problem.	Disconnect power, then reapply power. If condition persists, contact your home care provider for repair.

Consult your clinician to change any of the breathing parameters or alarm settings.

Patient and caregiver information

The following checklist presents topics that patients and caregivers must understand in order to use this device successfully. Some topics do not apply to some patients; some patients may require more information. It is the responsibility of the physician or clinical educator to ensure that the patient and caregiver understand the appropriate topics.

Table 5-1: Patient and caregiver checklist

The patient and caregiver must understand:	
❑	The need for bi-level ventilation.
❑	The schedule for ventilation.
❑	The supplies required for ventilation, and their sources.
❑	Whom to contact for medical emergencies, equipment emergencies, or power emergencies.
❑	How to contact other resources for assistance (health aides, attendants, therapists, and so on).
❑	The principles of operation for the bi-level ventilator.
❑	Power sources for the ventilator, and how to connect them.
❑	The bi-level ventilator parameter settings and the importance of each.
❑	How to perform a user self-test of the bi-level ventilator, and how to respond if the self-test fails.
❑	The ventilator alarm settings, and the purpose and function of each.
❑	How to respond to ventilator alarms.

Table 5-1: Patient and caregiver checklist (continued)

The patient and caregiver must understand:	
❏	What to do if the ventilator alarms inappropriately.
❏	The parts and purpose of the patient circuit.
❏	How and when to clean and replace the patient circuit.
❏	How to recognize and respond to problems with the patient circuit.
❏	The parts and purpose of the nasal interface or mask.
❏	Care of the nasal interface or mask.
❏	How to recognize and respond to problems with the nasal interface or mask.
❏	The oxygen setting, and why it is required.
❏	How to connect the oxygen source to the ventilator.
❏	How to determine the quantity of oxygen being delivered, and how to adjust the quantity.
❏	Safety rules for the use of oxygen.
❏	How and why to monitor the patient's condition.
❏	How to check the patient's vital signs.
❏	The significance of the patient's ease of breathing.
❏	What to note about the patient's skin, mucous membranes, and secretions, and their significance.
❏	How to recognize the signs of infection, and how to respond.
❏	The importance of routine medical appointments and medical testing.

Table 5-1: Patient and caregiver checklist (continued)

	The patient and caregiver must understand:
❏	Equipment and phone numbers to have available in cases of emergency.
❏	How to respond to dyspnea.
❏	How to recognize and respond to problems with the ventilator.
❏	How to recognize and respond to problems with the oxygen supply.
❏	Techniques to prevent aspiration of vomit.
❏	The importance of coordinating care for the patient.
❏	Resources for respite care.
❏	Choices about future care.
❏	The purpose of advanced directives.
❏	Replacement interval for outlet filters (per the filter manufacturer's instructions).

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EMC information

6.1 Manufacturer's Declaration

This section contains the manufacturer's declarations for the *KnightStar 330*'s electromagnetic emissions, electromagnetic immunity, recommended separation distances between portable and mobile RF communications equipment and the device, and a list of compliant cables and accessories. For more information regarding electromagnetic interference, see the warning on page 1-6.

Table 6-1: Electromagnetic emissions

The *KnightStar 330* is intended for use in the electromagnetic environment specified below. The customer or user of the *KnightStar 330* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *KnightStar 330* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The *KnightStar 330* is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class D	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 6-2: Electromagnetic immunity

The *KnightStar 330* is intended for use in the electromagnetic environment specified below. The customer or the user of the *KnightStar 330* should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T for 0.5 cycle) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) < 5% U_T (> 95% dip in U_T for 5 s)	< 5% U_T (> 95% dip in U_T for 0.5 cycle) 40% U_T (60% dip in U_T for 5 cycles) 70% U_T (30% dip in U_T for 25 cycles) < 5% U_T (> 95% dip in U_T for 5 s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *KnightStar 330* requires continued operation during power mains interruptions, it is recommended that the *KnightStar 330* be powered from an uninterruptible power supply or a battery.

Table 6-2: Electromagnetic immunity (continued)

The *KnightStar 330* is intended for use in the electromagnetic environment specified below. The customer or the user of the *KnightStar 330* should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

U_T is the AC mains voltage prior to application of the test level.

**Table 6-3: Electromagnetic immunity –
conducted and radiated RF**

The *KnightStar 330* is intended for use in the electromagnetic environment specified below. The customer or the user of the *KnightStar 330* should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the *KnightStar 330*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ [†] $d = 2.3\sqrt{P}$ [‡] where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

**Table 6-3: Electromagnetic immunity –
conducted and radiated RF (continued)**

The *KnightStar 330* is intended for use in the electromagnetic environment specified below. The customer or the user of the *KnightStar 330* should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Field strengths from fixed RF transmitters as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

> • **At 80 MHz and 800 MHz, the higher frequency range applies.**
>
> • **These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.**

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To asses the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *KnightStar 330* is used exceeds the applicable RF compliance level above, the *KnightStar 330* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *KnightStar 330*.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

† 80 MHz to 800 MHz
‡ 800 MHz to 2.5 GHz

Table 6-4: Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the *KnightStar 330*		
The *KnightStar 330* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *KnightStar 330* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *KnightStar 330* as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.		

- **At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.**

- **These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.**

Table 6-5: Compliant cables and accessories

The listed cables and accessories comply with the following standards:
- RF emissions, CISPR 11 Group, Class B
- EN 60601-1-2:2001

Cable or accessory	Maximum length
Cable, battery adapter, Y-102914-00	74 in (188 cm)
Cable, cigarette lighter adapter, Y-102913-00	74 in (188 cm)
KnightStar 330 Service Communications Cable, Y-103086-00A	72 in (183 cm)
KnightStar 330 Power cord, NEMA 1-15, Y-500012-00	80 in (203 cm)
KnightStar 330 Power cord, CEE 7/16, Y-500013-00	80 in (203 cm)
KnightStar 330 Power cord, UK, Y-500014-00	80 in (203 cm)

The use of accessories and cables other than those specified, with the exception of parts sold by Puritan Bennett as replacements for internal components, may result in increased emissions or decreased immunity of the *KnightStar 330*.

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